POSITION PAPER ON RISK ASSESSMENT OF LIVING MODIFIED ORGANISMS CONTAINING ENGINEERED GENE DRIVES

Gene drive approaches offer the potential to develop new tools to address important conservation and public health challenges that have not been successfully solved by current methods alone, such as vector-borne diseases and invasive alien species. Although research into synthetic gene drives is still at a relatively early stage, with no field evaluations planned in the medium-term, recent scientific progress in developing potential gene drive organisms has spurred increasing interest in the issue of governance and regulation of these technologies.

Questions regarding whether gene drive organisms can be developed, evaluated and used safely, and what the impacts of an eventual release might be, have been given an increasingly prominent place in the work of the UN Convention on Biological Diversity (CBD), the International Union for the Conservation of Nature (IUCN), and many other forums tasked with protecting the environment.

Decision CBD/CP/MOP/DEC/9/13 established an online forum and an Ad Hoc Technical Expert Group with the purpose of supporting deliberations by countries on the suitability of current guidance for risk assessment of gene drive organisms. The decision requested SBSTTA to make a recommendation as to “whether additional guidance materials on risk assessment are needed for (a) living modified organisms containing engineered gene drives” for consideration at CBD COP 15-MOP 10.
Deliberations at SBSTTA and COP-MOP 10 should take into account the following considerations:

Risk assessment will need to be carried out on a case-by-case basis

- As the study commissioned to address the application of Annex 1 to decision CP 9/13 took great pains to highlight, the different technologies, approaches, and proposed applications grouped under the term “gene drive” vary enormously. This means that their risk profiles and potential benefits will also vary hugely, making generalizations and conclusions applicable to all gene drives impossible. Consequently, risk assessment guidance that is generically applicable to gene drives will be of limited value, and given the pace of research developments in this field, is likely to be obsolete when adopted by the CBD. Instead, as the study and the submissions of many Parties note, a case-by-case approach to the risk assessment of LMOs containing engineered gene drives will need to be adopted. Assessments will need to be tailored to the specific organism being released and the proposed receiving environment.

There are tools and guidelines available to carry out accurate risk assessments of gene drive

- As noted by many Parties, in the study commissioned by the CBD Secretariat, by several participants in the Online Forum and by experts on the Ad Hoc Technical Expert Group (AHTEG), the current methodologies for risk assessment of LMOs are broadly adequate for organisms containing engineered gene drives.

- In many cases the identified challenges to accurately assessing risks relate not to the existing regulatory frameworks and other guidance, but rather to a lack of capacity or data in some contexts to be able to apply the guidance properly.

- Data gaps can be partially addressed through the use of appropriate comparators, of which many have been identified by researchers and regulators. Existing methods for control of disease vectors and invasive species will often have similar characteristics and impacts to proposed gene drive applications and can therefore be drawn upon for baseline data and to help inform future gene drive assessments.

Capacity-building for risk-assessment is a priority for Parties

- In submissions on their experiences, challenges and needs regarding LMOs containing engineered gene drives, the need for increased capacity-building was highlighted again and again by Parties to the Cartagena Protocol. Although Parties may acknowledge that adequate methodologies for risk assessment exist, many expressed the concern that they lack
the adequate resources and/or expertise (be they legal, scientific, procedural, or otherwise) to implement them.

• As the foremost international organization dealing with biodiversity and conservation, the CBD is centrally placed to facilitate this capacity-building among Parties. Knowledge-sharing, training, and other capacity-building activities should therefore be prioritized in its work.

The CBD must make the most efficient use of its limited resources

• Any efforts under the auspices of the CBD on developing new guidance for the risk of assessment of gene drive LMOs risks being duplicative and/or redundant, given the work already done at national level in many contexts on this topic and that being undertaken by other international organizations such as the IUCN and the World Health Organization (WHO). This would be a poor use of CBD resources, which are already under considerable strain. Therefore, the CBD should ensure that any work undertaken makes the best use of the assets available to it and responds to a genuine need on the part of Parties.

The only way to address existing uncertainties and data gaps is through further research

• As mentioned above, data gaps remain that may hamper the ability of Parties to carry out accurate risk assessments. The only way to address these gaps and other uncertainties is by fostering further research on gene drives.

• Any policies or measures that unnecessarily restrict gene drive research or prevent it from being carried out responsibly could undermine the ability of Parties to conduct risk assessments. They would therefore be counterproductive in ensuring that gene drives are investigated, evaluated, and potentially deployed safely.

For more information visit: www.genedrivenetwork.org